27-32 being withdrawn from further consideration under 37 C.F.R. § 1.142(b). Claims 1-4 and 10-12 have been amended and remain pending with claim 1 being independent. Claims 33-48 have been added with claims 34, 41 and 48 being independent and entry of the same is respectfully requested. No new matter has been added by this amendment.

I. The § 112 Rejections

A. Rejection of claims 1-4 and 10-12 under 35 U.S.C. § 112 ¶ 1.

The Examiner rejected claims 1-4 and 10-12 under 35 U.S.C. § 112 ¶ 1 as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states that "[o]ne of ordinary skill in the art would not know what constitute[s] 'cooperates' and how to achieve it." Applicant has therefore amended its claims to delete the term "cooperates" and respectfully requests reconsideration and withdrawal of this rejection under § 112. The Examiner also stated that melengestrol acetate would not be recognized as either estrus-suppressing or as an implant. Applicant submits herewith as Exhibit A a report from the U.S. Department of Agriculture describing melengestrol acetate as an estrus suppressant. Applicant also submits that it is known to those skilled in the art that melengestrol acetate can be provided to beef cattle or other food animals as an implant as well as a feed additive as shown by Exhibit B. Moreover, at page 5 of the Office Action, the Examiner cites the Ensminger reference as evidence that certain compounds, including melengestrol acetate, are used in implants. Applicant therefore respectfully requests reconsideration and withdrawal of this rejection under § 112.

B. Rejection of claims 2 and 11 under 35 U.S.C. § 112 ¶ 2.

The Examiner has rejected claims 2 and 11 under 35 U.S.C. § 112 ¶ 2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Specifically, the Examiner states that "bio effective derivatives" is indefinite. Applicant has therefore amended its claims to delete the terms "bio effective" and respectfully requests reconsideration and withdrawal of this rejection. The Examiner also appears to have rejected claim 11 asserting that claim 11 should be two claims with one directed solely to progestins. Applicant has therefore amended claim 11 and added new claim 33 directed to progestins and respectfully requests reconsideration and withdrawal of the rejection of claim 11.

II. The 35 U.S.C. § 102(b) Rejections

A. Rejection of claim 1 over Magruder et al.

The Examiner has rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,731,001 to Magruder et al.. Magruder describes a fluid-imbibing delivery device or dispenser for storing and protecting a fluid-sensitive active agent and for dispensing the agent to a fluid environment of use over a prolonged period of time. One of the preferred active agents disclosed is bovine somatotropin. The active agent formulation also can include a pharmaceutically acceptable carrier such as a buffer, viscosity modulating vehicle, surfactant, dyes and other additives known in the art.

Applicant respectfully submits that claim 1 is not anticipated by the Magruder reference because Magruder fails to include every element and limitation of this claim. The Examiner states that Magruder provides implants containing growth stimulating agents in solid bio-accessible form. However, this is not the substance of claim 1. Magruder does not disclose the combination of a growth stimulating agent and a supplemental agent for implantation which synergistically promote animal growth. Rather, Magruder patent merely provides a single osmotic delivery device for fluid-sensitive active agents such as growth promotants. There is no reference anywhere in Magruder to the effective combination of more than one active agent. The

Examiner further states claim 1 is anticipated because Magruder teaches subcutaneous implantation at column 7, lines 12-14. However, this subcutaneous implantation is expressly limited to implantation in the peritoneal (abdominal) cavity of an animal and not under the skin as claimed by Applicant. Magruder's failure to disclose implantation under the skin cannot be read back into the reference by implication. See In re Evanega, 4 USPQ2d 1249 (Fed. Cir. 1987). Thus, the '001 patent does not anticipate claim 1 and the claims depending therefrom.

B. Rejection of claims 1-4 and 11 over Cardamone et al.

The Examiner also rejected claims 1-4, 10 and 11 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,980,508 to Cardamone et al. Cardamone discloses a device for dispensing active agents wherein the active agent may be dispensed from the device as a solid, liquid or gas. The active agent may then be dispersed as a slurry, concentrated liquid or a tablet. Contrary to the Examiner's assertions, this reference does not disclose the synergistic combination of a growth stimulating agent with a supplemental agent to promote growth in an animal. The Examiner states that Cardamone discloses such a combination at column 5, bottom. However, the reference is to the suitability of the Cardamone delivery device for hormones, cytokines and vaccines. There is no teaching of a combination of these therapeutic agents. Further, the Examiner states that Fig. 2 shows multiple pellets (118) in an implant. However, reference sign 118 is not directed toward multiple pellets, but to the passive layers of the delivery device. As the Examiner stated, moreover, Fig. 2 and Example 1 only demonstrated delivery of a single therapeutic agent, namely, porcine growth hormone. Example 2, contrary to the Examiner's assertion, does not show a growth stimulating agent (porcine growth hormone) and cooperating agent (vaccine) in combination. Rather, the last paragraph of Example 2 merely states that vaccines may also be delivered via the delivery device in a manner similar to that of

porcine growth hormone. Example 2 therefore possesses no teaching or suggestion that the growth hormone and vaccine be combined.

In the Office Action at page 4, the Examiner also asserts that Example 6 shows a four-delivery-stage implant and that this implant is then used subcutaneously in sheep as shown at column 20. However, neither Example 6 nor the section entitled "In Vivo Testing" at column 20 disclose the delivery of more than one therapeutic agent. Rather, Cardamone only discloses that the sheep were implanted with delivery devices containing two tabletted doses of tetanus toxoid. Therefore, because Cardamone fails to teach each and every limitation of claim 1, Cardamone does not anticipate the present invention under § 102(e). Applicant respectfully requests reconsideration and withdrawal of this rejection.

C. Rejection of claims 1-4 over Runkel et al.

The Examiner has also rejected claims 1-4 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,035,891 to Runkel et al. Runkel describes a sustained release implant capable of releasing a therapeutic agent at a constant rate over a prolonged period of time wherein the implant swells through osmotic pressure after implantation to release the therapeutic agent. Runkel does not, however, teach the synergistic combination of a growth-promoting agent with a second, supplemental agent such as estrus-suppressing compositions or antibiotics as required by independent claim 1. The Examiner states that Runkel discloses trenbolone at 25 mg in combination with estrus suppressants at column 13. However, the only disclosure in column 13 is of the combination of trenbolone with other growth stimulating agents such as progesterone and estradiol benzoate. Neither in column 13 nor in the rest of the Runkel reference is there any disclosure whatsoever of a synergistic combination of a growth stimulating agent such as trenbolone, progesterone, or estradiol benzoate with a supplemental agent such as melengesterol acetate. Because Runkel fails to disclose every limitation of independent claim 1,

it does not anticipate this claim and the claims depending therefrom and cannot therefore cannot be used to support a rejection under § 102(b). Applicant respectfully requests that this rejection be withdrawn.

III. The 35 U.S.C. § 103(a) Rejection

The Examiner also rejected claims 1-4 and 10-12 under 35 U.S.C. § 103(a) as being unpatentable over Ensminger in view of Runkel, Samber and Cardamone. For the following reasons, Applicant respectfully submits that the present invention is not obvious under 35 U.S.C. § 103(a) and requests reconsideration and withdrawal of the § 103(a) rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

With respect to objective evidence of nonobviousness, Applicant submits that the record supports the conclusion that there are long-felt but unsolved needs met by the present invention. The present invention is directed to the particular problem and existing need for provision of a new and improved subcutaneous implant for implanting under the skin of an animal which provides a synergistic benefit from the combination of a growth stimulating agent and a supplemental agent. None of the cited references teach or suggest the claimed invention. As discussed above in connection with the § 102 rejections of Applicant's claims based upon these references, there is no teaching or suggestion of administering a synergistically effective amount

of a growth stimulating agent and a synergistically effective amount of a supplemental agent such that the combination promotes the growth of an animal.

Turning to the primary reference cited by the Examiner, the Ensminger reference merely discloses the use of growth and other hormones as implants. Ensminger does not teach or suggest that growth hormones when combined with another synergistically cooperative agent will promote animal growth. Similarly, the '891 patent to Runkel merely discloses a novel delivery device for the delivery of known growth promotants to animals. As discussed above, there is no disclosure whatsoever in Runkel of a synergistic combination of growth stimulating agents with melengestrol acetate or other supplemental agent. In the Office Action at page 5, line 10, the Examiner confirms that "Runhel [sic] doesn't specify MGA." The Examiner also states that the Ensminger reference discloses use of MGA as a feed additive and therefore concludes that it would be obvious to one skilled in the art to combine these references. However, even the indiscriminate combination of Runkel and Ensminger does not meet the limitations of the claimed invention which requires the synergistic combination of growth promotants and MGA or another cooperative agent. The fact that there is no teaching or suggestion in Runkel to combine the growth hormones described in Ensminger with another, synergistically cooperative, therapeutic agent contributes to the conclusion that Applicant's invention is not obvious.

The Examiner also cited Samber et al. as a reference, but did not provide Applicant with any reasons why Samber renders the present invention obvious. Samber merely describes a study of cattle treated with growth promoting implants and does not teach or suggest the synergistic combination of the present application. The Examiner concludes by stating that it would be "obvious to use a multiple dosage paired delivery system as of Cardamone in order to provide a pellet of MGA in female cattle to suppress estrus, while a second pellet with faster

release would be loaded with Trenbalene [sic] to maximize growth promotion." (Page 5, lines 14-17). However, as discussed above, because there was no teaching or suggestion in Ensminger, Runkel, Samber or Cardamone to combine growth promotants with melengestrol acetate or other estrus-suppressing compositions to promote better animal growth, it is inapposite to conclude that Cardamone's multi-stage delivery device renders the present invention obvious.

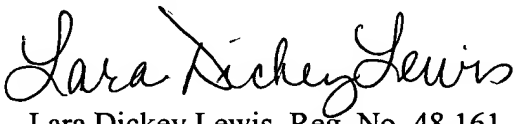
Finally, prima facie obviousness requires that there must be a reasonable expectation of success when prior art is modified or combined. In the present application, there is no reasonable expectation of success in achieving the invention as claimed when the cited references are modified or combined. As discussed above, none of the cited references contain all the elements of Applicants' independent claim 1. Unless all the elements are taught by the references, there can be no success in modifying them.

Thus, at the time the present invention was made, none of the references cited by the Examiner teach or describe *all* of the limitations claimed by Applicant in independent claim 1 and the claims depending therefrom. It would therefore not have been obvious to one of ordinary skill in the art to provide an implant for subcutaneous placement in the ear of an animal having both a growth stimulating agent and a supplemental agent that synergistically combine to promote growth in animals. Accordingly, independent claim 1 and the claims depending therefrom are nonobvious under § 103 (a).

IV. Conclusion

The applicant respectfully requests withdrawal of the rejections and believes that the claims as presented are now in condition for allowance. However, if the Examiner desires, the applicant is ready for a telephone interview to expedite prosecution. As always, the Examiner is free to call the undersigned at 816-460-2516. The Examiner's attention is also drawn to the proper correspondence address shown below.

Respectfully submitted,
SONNENSCHEIN NATH & ROSENTHAL

By 

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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN CLAIMS

Claims 1-4 and 10-12 have been amended as follows:

1. A [growth promoting] solid bio-accessible implant for placement [in a solid bio-accessible form] under the skin of an animal[; said implant] comprising:

[a)] a synergistically effective amount of a growth stimulating agent; and

[b)] a synergistically effective amount of a supplemental agent;

[that cooperates with said growth stimulating agent] wherein said agents synergistically combine to promote growth in an animal.

2. The implant according to claim 1 wherein[: a)] said growth stimulating agent is selected from the group consisting of trenbolone acetate, estradiol, estradiol benzoate, zeranol, testosterone propionate, progesterone [mixtures and bio-effective] derivatives and combinations thereof.

3. The implant according to claim 1 wherein[: a)] said supplemental agent is [chosen] selected from the group consisting of parasiticides, estrus-suppressing compositions, antibiotics, somatotropins, gonadotropins, derivatives and [mixtures] combinations thereof.

4. The implant according to claim [3] 1 wherein[: a)] at least one of said agents includes [both] an immediate release component and at least one of said agents includes a time-delayed component.

10. The implant according to claim 1 wherein[: a)] said growth stimulating agent and said supplemental agent are in separate pellets of said implant.

11. The implant according to claim 3 wherein[: a)] said estrus-suppressing composition is [chosen] selected from the group consisting [essentially] of melengesterol acetate, norgestomet[, other progestins, mixtures and bio-effective] derivatives and combinations thereof.

12. The implant according to claim 1 wherein[: a)] said growth stimulating agent [is] comprises from about 5 to 400 mg trenbolone acetate [in a dosage amount in the range from about 20 to 400 milligrams per implant;] and [b)] said [estrus suppressing composition is] supplemental agent comprises from about 10 to 100 mg melengesterol acetate [in a dosage amount in the range from about 10 to 100 milligrams per implant].

APPENDIX B
NEW CLAIMS

33. The implant according to claim 3 wherein said estrus-suppressing composition is a progestin.

34. An implant for placement under the skin of an animal comprising:
at least one solid bio-accessible pellet having a synergistically effective amount of a growth stimulating agent; and
at least one solid bio-accessible pellet having a synergistically effective amount of a supplemental agent;
wherein said pellets synergistically combine to promote growth in an animal.

35. The implant according to claim 34 wherein said growth stimulating agent is selected from the group consisting of trenbolone acetate, estradiol, estradiol benzoate, zeranol, testosterone propionate, progesterone, derivatives and combinations thereof.

36. The implant according to claim 34 wherein said supplemental agent is selected from the group consisting of parasiticides, estrus-suppressing compositions, antibiotics, somatotropins, gonadotropins, derivatives and combinations thereof.

37. The implant according to claim 34 wherein at least one of said agents includes an immediate release component and at least one of said agents includes a time-delayed component.

38. The implant according to claim 36 wherein said estrus-suppressing composition is selected from the group consisting of melengestrol acetate, norgestomet, derivatives and combinations thereof.

39. The implant according to claim 36 wherein said estrus-suppressing composition is a progestin.

40. The implant according to claim 34 wherein said growth stimulating agent comprises from about 20 to 400 mg trenbolone acetate and said supplemental agent comprises from about 10 to 100 mg melengestrol acetate.

41. A method for promoting growth in animals comprising:

providing at least one solid bio-accessible pellet having a synergistically effective amount of a growth stimulating agent;

providing at least one solid bio-accessible pellet having a synergistically effective amount of a supplemental agent wherein said pellets synergistically combine to promote growth in an animal; and

implanting said first and second pellets under the skin of an animal.

42. The method according to claim 41 wherein said growth stimulating agent is selected from the group consisting of trenbolone acetate, estradiol, estradiol benzoate, zeranol, testosterone propionate, progesterone, derivatives and combinations thereof.

43. The method according to claim 41 wherein said supplemental agent is selected from the group consisting of parasiticides, estrus-suppressing compositions, antibiotics, somatotropins, gonadotropins, derivatives and combinations thereof.

44. The method according to claim 41 wherein at least one of said pellets includes both an immediate release component and a time-delayed component.

45. The method according to claim 43 wherein said estrus-suppressing composition is selected from the group consisting of melengesterol acetate, norgestomet, derivatives and combinations thereof.

46. The method according to claim 43 wherein said estrus-suppressing composition is a progestin.

47. The method according to claim 41 wherein said growth stimulating agent comprises from about 5 to 400 mg trenbolone acetate and said supplemental agent comprises from about 10 to 100 mg melengesterol acetate.

48. An implant for placement under the skin of an animal comprising:

at least one solid bio-accessible pellet having a synergistically effective amount of trenbolone acetate; and

at least one solid bio-accessible pellet having a synergistically effective amount of melengestrol acetate;

wherein said pellets synergistically combine to promote growth in an animal.

EXHIBIT
A

Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Consumer Education and Information

Slightly Revised June 2002

FOCUS ON: BEEF . . . *from Farm to Table*

Since 1910, the first year that statistics were compiled, Americans have been eating an average of 60 pounds of beef yearly. About 36 million cattle were inspected in 1997 alone by USDA's Food Safety and Inspection Service. This translates into 64 pounds of beef per person in 1997. In calls to the Hotline, beef is the third food category (behind turkey and chicken) callers most ask about. The following information answers many of their questions.

What is Beef?

The domestication of cattle for food dates to about 6500 B.C. in the Middle East. Cattle were not native America, but brought to the New World on ships by European colonists. Americans weren't big eaters of fresh beef until about 1870, due to the enormous growth of the cattle industry in the West. The introduction of cattle cars and refrigerated cars on the railroad facilitated distribution of the beef.

"Beef" is meat from full-grown cattle about 2 years old. A live steer weighs about 1,000 pounds and yields about 450 pounds of edible meat. There are at least 50 breeds of beef cattle, but fewer than 10 make up most cattle produced. Some major breeds are Angus, Hereford, Charolais, and Brahman.

"Baby beef" and "calf" are 2 interchangeable terms used to describe young cattle weighing about 700 pounds that have been raised mainly on milk and grass. The meat cuts from baby beef are smaller; the meat is light red and contains less fat than beef. The fat may have a yellow tint due to the vitamin A in grass.

"Veal" is meat from a calf which weighs about 150 pounds. Those that are mainly milk-fed usually are less than 3 months old. The difference between "veal" and "calf" is based on the color of their meat, which is determined almost entirely by diet. Veal is pale pink and contains more cholesterol than beef.

NOTE: This information is about whole muscle beef and variety beef. See "Focus on Ground Beef" for information about hamburger and ground beef.

How are Cattle Raised?

All cattle start out eating grass; three-fourths of them are "finished" (grown to maturity) in feedlots where they are fed specially formulated feed based on corn or other grains.

Can Hormones and Antibiotics Be Used in Cattle Raising?

Antibiotics may be given to prevent or treat disease in cattle. A "withdrawal" period is required from the time antibiotics are administered until it is legal to slaughter the animal. This is so residues can exit the animal's system. FSIS randomly samples cattle at slaughter and tests for residues. Data from this

Monitoring Plan have shown a very low percentage of residue violations. Not all antibiotics are approved for use in all classes of cattle. However, if there is a demonstrated theraputic need, a veterinarian may prescribe an antibiotic that is approved in other classes for an animal in a non-approved class. In this case no detectable resides of this drug may be present in the edible tissues of the animal at slaughter.

Hormones may be used to promote efficient growth. Estradiol, progesterone, and testosterone (three natural hormones), and zeranol and trenbolone acetate (two synthetic hormones) may be used as an implant on the animal's ear. The hormone is time released, and is effective for 90 to 120 days. In addition melengesterol acetate, which can be used to supress estrus, or improve weight gain and feed efficiency, is approved for use as a feed additive. Not all combinations of hormones are approved for use in all classes of cattle. Hormones are approved for specific classes of animals only, and cannot be used in non-approved classes.

How is Beef Inspected?

All beef found in retail stores is either USDA inspected for wholesomeness or inspected by state systems which have standards equal to the Federal government. Each steer and its internal organs are inspected for signs of disease. The "Passed and Inspected by USDA" seal insures the beef is wholesome and free from disease.

What Does the Grade Mean?

Inspection is mandatory; grading is voluntary, and a plant pays to have its meat graded. USDA-graded beef sold at the retail level is Prime, Choice, and Select. Lower grades (Standard, Commercial, Utility, Cutter, and Canner) are mainly ground or used in processed meat products. Retail stores may use other terms which must be different from USDA grades.

USDA Prime beef (about two percent of graded beef) has more fat marbling, so it is the most tender and flavorful. However, it is higher in fat content. Most of the graded beef sold in supermarkets is USDA Choice or USDA Select. The protein, vitamin, and mineral content of beef are similar regardless of the grade.

How Is Ungraded Beef Different?

All beef is inspected for wholesomeness. The overall quality of ungraded beef may be higher or lower than most government grades found in retail markets.

What is Marbling?

Marbling is white flecks of fat within the meat muscle. The greater amount of marbling in beef, the higher the grade because marbling makes beef more tender, flavorful, and juicy.

Retail Cuts of Fresh Beef

There are four basic major (primal) cuts into which beef is separated: chuck, loin, rib, and round. It is recommended that packages of fresh beef purchased in the supermarket be labeled with the primal cut as well as the product, such as "chuck roast" or "round steak." This helps consumers know what type of heat is best for cooking the product. Generally, chuck and round are less tender and require moist heat such as braising; loin and rib can be cooked by dry heat methods such as broiling or grilling.

Unfortunately, names for various cuts can vary regionally in stores, causing confusion over the choice of cooking method. For example, a boneless top loin steak is variously called: strip steak, Kansas City Steak, N.Y. strip steak, hotel cut strip steak, ambassador steak, or club sirloin steak.

How Much Beef Is Consumed?

Figures from the USDA's Economic Research Service show average annual per capita beef consumption for the following selected periods:

1910-15	51 pounds	1960-65	69 pounds
1920-25	46 pounds	1970-75	85 pounds
1930-35	41 pounds	1980-85	78 pounds
1940-45	45 pounds	1990-95	67 pounds
1950-55	55 pounds	1995-97	64 pounds

Nutrition

Nutrient data on beef can be found in the USDA Agricultural Research Service's Food Composition Database at www.nal.usda.gov/fnic/foodcomp/index.html

Nutrition Labeling

Nutrition claims such as "lean" and "extra lean" are sometimes seen on beef products. Here are their definitions:

"Lean" - 100 grams of beef with less than 10 grams of fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol.

"Extra Lean" - 100 grams of beef with less than 5 grams of fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol.

What Does "Natural" Mean?

All fresh meat qualifies as "natural." Products labeled "natural" cannot contain any artificial flavor or flavoring, coloring ingredient, chemical preservative, or any other artificial or synthetic ingredient; and the product and its ingredients are not more than minimally processed (ground, for example). All product claiming to be natural should be accompanied by a brief statement which explains what is meant by the term "natural."

Some companies promote their beef as "natural" because they claim their cattle weren't exposed to antibiotics or hormones and were totally raised on a range instead of being "finished" in a feedlot.

How and Why is Some Beef Aged?

Beef is aged to develop additional tenderness and flavor. It is done commercially under controlled temperatures and humidity. Since aging can take from 10 days to 6 weeks, **the USDA does not**

recommend aging beef in a home refrigerator.

Why is Beef Called a "Red" Meat?

Oxygen is delivered to muscles by the red cells in the blood. One of the proteins in meat, myoglobin, holds the oxygen in the muscle. The amount of myoglobin in animal muscles determines the color of meat. Beef is called a "red" meat because it contains more myoglobin than chicken or fish. Other "red" meats are veal, lamb, and pork.

Color of Beef

Beef muscle meat not exposed to oxygen (in vacuum packaging, for example) is a burgundy or purplish color. After exposure to the air for 15 minutes or so, the myoglobin receives oxygen and the meat turns bright, cherry red.

After beef has been refrigerated about 5 days, it may turn brown due to chemical changes in the myoglobin. Beef that has turned brown during extended storage may be spoiled, have an off-odor, and be tacky to the touch.

Iridescent Color of Roast Beef

Sliced cooked beef or lunch meat can have an iridescent color. Meat contains iron, fat, and many other compounds. When light hits a slice of meat, it splits into colors like a rainbow. There are also various pigments in meat compounds which can give it an iridescent or greenish cast when exposed to heat and processing. Iridescent beef isn't spoiled necessarily. Spoiled cooked beef would probably also be slimy o sticky and have an off-odor.

Additives

Additives are not allowed on fresh beef. If beef is processed, additives such as MSG, salt, or sodium erythorbate must be listed on the label.

Dating of Beef Products

Product dating is not required by Federal regulations. However, many stores and processors may voluntarily date packages of raw beef or processed beef products. If a calendar date is shown, there must be a phrase explaining the meaning of the date.

Use or freeze products with a "Sell-By" date within 3 to 5 days of purchase. If the manufacturer has determined a "Use-By" date, observe it. This is a quality assurance date after which peak quality begins t lessen but the product may still be used. It's always best to buy a product before its date expires. It's not important if a date expires after freezing beef because all foods stay safe while properly frozen.

What Foodborne Organisms are Associated with Beef?

Escherichia coli can colonize in the intestines of animals, which could contaminate muscle meat at slaughter. *E. coli* O157:H7 is a rare strain that produces large quantities of a potent toxin that forms in and causes severe damage to the lining of the intestine. The disease produced by it is called Hemorrhagic Colitis and is characterized by bloody diarrhea. *E. coli* O157:H7 is easily destroyed by thorough cooking

Salmonella may be found in the intestinal tracts of livestock, poultry, dogs, cats, and other warm-blooded animals. There are about 2,000 *Salmonella* bacterial species. Freezing doesn't kill this microorganism, but it is destroyed by thorough cooking. *Salmonella* must be eaten to cause illness. They cannot enter the body through a skin cut. Cross-contamination can occur if raw meat or its juices contact cooked food or foods that will be eaten raw, such as salad.

Staphylococcus aureus can be carried on human hands, nasal passages, or throats. Most foodborne illness outbreaks are a result of contamination from food handlers and production of a heat-stable toxin in the food. Sanitary food handling and proper cooking and refrigerating should prevent staphylococcal foodborne illness.

Listeria monocytogenes is destroyed by cooking, but a cooked product can be recontaminated by poor handling practices and poor sanitation. FSIS has a zero tolerance for *Listeria monocytogenes* in cooked and ready-to-eat products such as beef franks or lunchmeat. Observe handling information such as "Keep Refrigerated" and "Use-By" dates on labels.

Rinsing Beef

It isn't necessary to wash raw beef before cooking it. Any bacteria which might be present on the surface would be destroyed by cooking.

How to Handle Beef Safely

Raw Beef. Select beef just before checking out at the register. Put packages of raw beef in disposable plastic bags, if available, to contain any leakage which could cross-contaminate cooked foods or produce Beef, a perishable product, is kept cold during store distribution to retard the growth of bacteria.

Take beef home immediately and refrigerate it at 40 °F; **use within 3 to 5 days** (1 or 2 days for variety meats such as liver, kidneys, tripe, sweetbreads, or tongue) or freeze (0 °F). If kept frozen continuously, it will be safe indefinitely.

It is safe to freeze beef in its original packaging or repackage it. However, for long-term freezing, overwrap the porous store plastic with aluminum foil, freezer paper, or freezer-weight plastic wrap or bags to prevent "freezer burn," which appears as grayish-brown leathery spots and is caused by air reaching the surface of food. Cut freezer-burned portions away either before or after cooking the beef. Heavily freezer-burned products may have to be discarded for quality reasons. For best quality, use steak and roasts within 9 to 12 months.**Ready-Prepared Beef.** For fully-cooked, take-out beef dishes such as Chinese food, barbecued ribs, or fast food hamburgers, be sure they are hot at pickup. Use cooked beef within 2 hours (1 hour if the air temperature is above 90 °F) or **refrigerate it at 40 °F in shallow, covered containers**. Eat within 3 to 4 days, either cold or reheated to 165 °F (hot and steaming). It is safe to freeze ready-prepared beef dishes. For best quality, use within 4 months.

Safe Defrosting

There are three safe ways to defrost beef: in the refrigerator, in cold water, and in the microwave. Never defrost on the counter or in other locations.

Refrigerator. It's best to plan ahead for slow, safe thawing in the refrigerator. Ground beef, stew meat, and steaks may defrost within a day. Bone-in parts and whole roasts may take 2 days or longer. Once the raw beef defrosts, it will be safe in the refrigerator for 3 to 5 days before cooking. During this time, if you

decide not to use the beef, **you can safely refreeze it without cooking it first.**

Cold Water. To defrost beef in cold water, do not remove packaging. Be sure the package is airtight or put it into a leakproof bag. Submerge the beef in cold water, changing the water every 30 minutes so that it continues to thaw. Small packages of beef may defrost in an hour or less; a 3- to 4-pound roast may take 2 to 3 hours.

Microwave. When microwave defrosting beef, plan to cook it immediately after thawing because some areas of the food may become warm and begin to cook during microwaving. Holding partially-cooked food is not recommended because any bacteria present wouldn't have been destroyed.

Foods defrosted in the microwave or by the cold water method should be cooked before refreezing because they may have been held at temperatures above 40 °F.

It is safe to cook frozen beef in the oven, on the stove, or grill without defrosting it first; the cooking time may be about 50% longer. Do not cook frozen beef in a slow cooker.

Marinating

Marinate beef in the refrigerator up to 5 days. Boil used marinade before brushing on cooked beef. Discard any uncooked leftover marinade.

Partial Cooking

Never brown or partially cook beef to refrigerate and finish cooking later because any bacteria present wouldn't have been destroyed. It is safe to partially pre-cook or microwave beef **immediately** before transferring it to the hot grill to finish cooking.

Liquid in Package

Many people think the red liquid in packaged fresh beef is blood. However, blood is removed from beef during slaughter and only a small amount remains within the muscle tissue. Since beef is about 3/4 water this natural moisture combined with protein is the source of the liquid in the package.

Safe Cooking

For safety, the USDA recommends cooking hamburgers and ground beef mixtures such as meat loaf to **160 °F** on a meat thermometer. However, whole muscle meats such as steaks and roasts may be cooked to **145 °F** (medium rare), **160 °F** (medium), **170 °F** (well done). For approximate cooking times for use in meal planning, see the following chart compiled from various resources.

Times are based on beef at refrigerator temperature (40 °F). Remember that appliances and outdoor grills can vary in heat. Use a meat thermometer to check for safe cooking and doneness of beef.

APPROXIMATE BEEF COOKING TIMES (°F)

TYPE OF BEEF	SIZE	COOKING METHOD	COOKING TIME	INTERNAL TEMPERATURE

Rib Roast, bone in	4 to 6 lbs.	Roast 325°	23-25 min./lb.	Medium rare 145°
			27-30 min./lb.	Medium 160°
			32-34 min./lb.	Well done 170°
Rib Roast, boneless rolled	4 to 6 lbs.	Roast 325°	Add 5-8 min./lb. to times above	Same as above
Chuck Roast, Brisket	3 to 4 lbs.	*Braise 325°	2 to 3 hours	Medium 160°
Round or Rump Roast	2 1/2 to 4 lbs.	Roast 325°	30-35 min./lb.	Medium rare 145°
			35-40 min./lb.	Medium 160°
Tenderloin, whole half	4 to 6 lbs.	Roast 425°	45-60 min. total	Medium rare 145°
	2 to 3 lbs.		35-45 min. total	Medium 160°
Steaks	3/4" thick	Broil/Grill	4-5 min. per side	Medium rare 145°
			6-7 min. per side	Medium 160°
Stew or Shank Cross Cuts	1 to 1 1/2" thick	Cover with liquid; simmer	2 to 3 hours	Medium 160°
Short Ribs	4" long and 2" thick	*Braise 325°	1 1/2 to 2 1/2 hours	Medium160°

*Braising is roasting or simmering less-tender meats with a small amount of liquid in a tightly covered pan.

MICROWAVE DIRECTIONS:

- When microwaving unequal size pieces of beef, arrange in dish or on rack so thick parts are toward the outside of dish and thin parts are in the center; cook on medium-high or medium power.
- Place a roast in an oven cooking bag or in a covered pot.
- Refer to the manufacturer's directions that accompany the microwave oven for suggested cooking times.
- Use a meat thermometer to test for doneness in several places to be sure temperatures listed above have been reached.

Storage Times

Since product dates aren't a guide for safe use of a product, how long can the consumer store the food and

still use it at top quality? Follow these tips:

- Purchase the product before the date expires.
- Follow handling recommendations on product.
- Keep beef in its package until using.
- It is safe to freeze beef in its original packaging. If freezing longer than 2 months, overwrap these packages with airtight heavy-duty foil, plastic wrap, or freezer paper or place the package inside a plastic bag.
- For storage times, consult the following chart.

HOME STORAGE OF BEEF PRODUCTS

If product has a "Use-By" Date, follow that date. If product has a "Sell-By" Date or no date, cook or freeze the product by the times on the following chart.

PRODUCT	REFRIGERATOR 40 ° F	FREEZER 0 °F
Fresh beef roast, steaks, chops, or ribs	3 to 5 days	6 to 12 months
Fresh beef liver or variety meats	1 or 2 days	3 to 4 months
Home cooked beef, soups, stews or casseroles	3 to 4 days	2 to 3 months
Store-cooked convenience meals	1 to 2 days	2 to 3 months
Cooked beef gravy or beef broth	1 or 2 days	2 to 3 months
Beef hot dogs or lunch meats, sealed in package	2 weeks (or 1 week after a "Use-By" date)	1 to 2 months
Beef hot dogs, opened package	7 days	1 to 2 months
Lunch meats, opened package	3 to 5 days	1 to 2 months
TV dinners, frozen casseroles	Keep Frozen	3 to 4 months
Canned beef products in pantry	2 to 5 years in pantry; 3 to 4 days after opening	After opening, 2 to 3 months
Jerky, commercially vacuum packaged home dried	1 year in pantry Refrigerate 2 to 3 months	Do not freeze

For additional food safety information about meat, poultry, or egg products, call the toll-free USDA Meat and Poultry Hotline at 1 (800) 535-4555; Washington, DC area, (202) 720-3333; for the hearing-impaired (TTY) 1 (800) 256-7072. The Hotline is staffed by food safety experts weekdays

from 10 a.m. to 4 p.m. Eastern time. Food safety recordings can be heard 24 hours a day using a touch-tone phone.

The media may contact the USDA Meat and Poultry Hotline at (202) 720-5604.

Information is also available from the FSIS Web site: http://www.fsis.usda.gov

The USDA is an equal opportunity provider and employer.

For Further Information Contact:
FSIS Food Safety Education Staff
Meat and Poultry Hotline:

- 1-800-535-4555 (Tollfree Nationwide)
- (202) 720-3333 (Washington, DC area)
- 1-800-256-7072 (TDD/TTY)
- E-mail: mphotline.fsis@usda.gov

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EXHIBIT
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June 2000
FACT SHEET #37

Cornell University Program on
Breast Cancer and Environmental Risk Factors
in New York State (BCERF)

Consumer Concerns About Hormones in Food

This fact sheet addresses some of the consumer concerns that have been brought to BCERF regarding health effects of hormones used by the meat and dairy industries. Evidence available so far, though not conclusive, does not link hormone residues in meat or milk with any human health effect.

What are hormones?

Hormones are chemicals that are produced naturally in the bodies of all animals, including humans. They are chemical messages released into the blood by hormone-producing organs that travel to and affect different parts of the body. Hormones may be produced in small amounts, but they control important body functions such as growth, development and reproduction.

Hormones can have different chemistry. They can be steroids or proteins. Steroid hormones are active in the body when eaten. For example, birth control pills are steroid hormones and can be taken orally. In contrast, protein hormones are broken down in the stomach, and lose their ability to act in the body when eaten. Therefore, ordinarily, protein hormones need to be injected into the body to have an effect. For example, insulin is a protein hormone. Diabetic patients need to be injected with insulin for treatment.

Why are hormones used in food production?

Certain hormones can make young animals gain weight faster. They help reduce the waiting time and the amount of feed eaten by an animal before slaughter in meat industries. In dairy cows, hormones can be used to increase milk production. Thus, hormones can increase the profitability of the meat and dairy industries.

Why are consumers concerned about hormones in foods?

While a variety of hormones are produced by our bodies and are essential for normal development of healthy tissues, synthetic steroid hormones used as pharmaceutical drugs, have been found to affect cancer risk. For example, diethylstilbestrol (DES), a synthetic estrogen drug used in the 1960s was withdrawn from use after it was found to increase the risk of vaginal cancer in daughters of treated women. Lifetime exposure to natural steroid hormone estrogen is also associated with an increased risk for breast cancer (see BCERF Fact Sheet #9 *Estrogen and Breast Cancer Risk: What is the Relationship?*). Hence, consumers are concerned about whether they are being exposed to hormones used to treat animals, and whether these hormones affect human health. We try to address this complex issue based on scientific evidence that is currently available.

History of hormone use in food production

As early as the 1930s, it was realized that cows injected with material drawn from bovine (cow) pituitary glands (hormone secreting organ) produced more milk. Later, the bovine growth hormone (bGH) from the pituitary glands was found to be responsible for this effect. However, at that time, technology did not exist to harvest enough of this material for large-scale use in animals. In

the 1980s, it became possible to produce large quantities of pure bGH by using recombinant DNA technology. In 1993, the Food and Drug Administration (FDA) approved the recombinant bovine growth hormone (rbGH), also known as bovine somatotropin (rbST) for use in dairy cattle. Recent estimates by the manufacturer of this hormone indicate that 30% of the cows in the United States (US) may be treated with rbGH.

The female sex hormone estrogen was also shown to affect growth rates in cattle and poultry in the 1930s. Once the chemistry of estrogen was understood, it became possible to make the hormone synthetically in large amounts. Synthetic estrogens started being used to increase the size of cattle and chickens in the early 1950s. DES was one of the first synthetic estrogens made and used commercially in the US to fatten chickens. DES was also used as a drug in human medicine. DES was found to cause cancer and its use in food production was phased out in the late 1970s.

What are the different hormones used now by the meat and dairy industries?

There are six different kinds of steroid hormones that are currently approved by FDA for use in food production in the US: estradiol, progesterone, testosterone, zeranol, trenbolone acetate, and melengestrol acetate. Estradiol and progesterone are natural female sex hormones; testosterone is the natural male sex hormone; zeranol, trenbolone acetate and melengesterol acetate are synthetic growth promoters (hormone-like chemicals that can make animals grow faster). Currently, federal regulations allow these hormones to be used on growing cattle and sheep, but not on poultry (chickens, turkeys, ducks) or hogs (pigs). The above hormones are not as useful in increasing weight gain of poultry or hogs.

As mentioned earlier, FDA allows the use of the protein hormone rbGH to increase milk production in dairy cattle. This protein hormone is not used on beef cattle.

How are the hormones introduced into the animals?

Steroid hormones are usually released into the animal from a pellet (ear implant) that is put under the skin of the ear. The ears of the animals are thrown away at slaughter. Improper use of pellet implants in other parts of the animal can result in higher levels of hormone residues to remain in the edible meat. Federal regulations prohibit their use in this manner. Melengestrol acetate is also available in a form that can be added to animal feed.

Dairy cattle may be injected under the skin with rbGH. This hormone is available in packages of single dose injections to reduce chances of accidental overdose.

Do federal agencies monitor for the presence of these hormones in food?

Estradiol, progesterone and testosterone are sex hormones that are made naturally by animals. No regulatory monitoring of these hormones is possible, since it is not possible to separate or tell the difference between the hormones used for treatment from those made by the animal's own body. However, it is possible to detect residues of zeranol and trembolone acetate in the animal's meat. FDA has set the tolerance levels for these hormones. A tolerance is the maximum amount of a particular residue that may be permitted in or on food (see BCERF Fact Sheet #25 on *Pesticide Residue Monitoring and Food Safety*). The Food Safety Inspection Service (FSIS) of the US Department of Agriculture (USDA) monitors meat from cattle for zeranol residues. FSIS also monitors meats for DES residues from any illegal use (DES use is no longer permitted). In response to concern about cases of early puberty in Puerto Rico described below, a large number of meat samples were tested for hormone residues in the mid- to late 1980s. No zeranol or DES residues were found in the meat samples in this survey.

Do hormones remain in the milk or meat of treated animals?

The levels of naturally produced hormones vary from animal to animal, and a range in these levels is known to be normal. Because it is not possible to differentiate between the hormones produced naturally by the animal and those used to treat the animal, it is difficult to determine exactly how much of the hormone used for treatment remains in the meat or the milk. Studies indicate that if correct treatment and slaughter procedures

are followed, the levels of these hormones may be slightly higher in the treated animal's meat or milk, but are still within the normal range of natural variation known to occur in untreated animals. Scientists are currently trying to develop better methods to measure steroid hormone residues left in edible meat from a treated animal.

Can steroid hormones in meat affect the age of puberty for girls?

Early puberty in girls has been found to be associated with a higher risk for breast cancer. Height, weight, diet, exercise, and family history have all been found to influence age of puberty (see BCERF Fact Sheet #8, *Childhood Life Events and the Risk of Breast Cancer*). Steroid hormones in food were suspected to cause early puberty in girls in some reports. However, exposure to higher than natural levels of steroid hormones through hormone-treated meat or poultry has never been documented. Large epidemiological studies have not been done to see whether or not early puberty in developing girls is associated with having eaten growth hormone-treated foods.

A concern about an increase in cases of girls reaching puberty or menarche early (at age eight or younger) in Puerto Rico, led to an investigation in the early 1980s by the Centers for Disease Control (CDC). Samples of meat and chicken from Puerto Rico were tested for steroid hormone residues. One laboratory found a chicken sample from a local market to have higher than normal level of estrogen. Also, residues of zeranol were reported in the blood of some of the girls who had reached puberty early. However, these results could not be verified by other laboratories. Following CDC's investigation, USDA tested 150 to 200 beef, poultry and milk samples from Puerto Rico in 1985, and found no residues of DES, zeranol or estrogen in these samples.

In another study in Italy, steroid hormone residues in beef and poultry in school meals were suspected as the cause of breast enlargement in very young girls and boys. However, the suspect beef and poultry samples were not available to test for the presence of hormones. Without proof that exposure to higher levels of steroid hormones occurred through food, it is not possible to conclude whether or not eating hormone-treated meat or poultry caused the breast enlargement in these cases.

Can eating meat from hormone-treated animals affect breast cancer risk?

Evidence does not exist to answer this question. The amount of steroid hormone that is eaten through meat of a treated animal is negligible compared to what the human body produces each day. The breast cancer risk of women who eat meat from hormone-treated animals has not been compared with the risk of women who eat meat from untreated animals.

Can drinking milk, or eating dairy products from hormone-treated animals affect breast cancer risk?

Once again, evidence does not exist to answer this question. Use of rbGH for dairy cattle has been in practice in US for only six to seven years. Breast cancer can take many years to develop. It is too early to study the breast cancer risk of women who drink milk and eat milk products from hormone-treated animals.

Can hormones that remain in milk affect human health?

Scientists at FDA's Center for Veterinary Medicine have reviewed the studies submitted by the manufacturers of rbGH. FDA scientists have concluded that eating foods with slightly higher levels of rbGH would not affect human health. This is because the amount of rbGH that is in milk or milk products as a result of treatment of the animals is insignificant compared to the amount of growth hormone that is naturally produced by our bodies. Also, rbGH is a protein hormone and is digested into smaller fragments (peptides and amino acids) when eaten. The rbGH hormone used on dairy cattle is effective in promoting growth in cows, but does not work in humans. Scientists know that rbGH is not recognized as a hormone by human cells.

There are gaps in our knowledge about whether rbGH used to treat dairy cattle can cause indirect effects. These gaps lead to uncertainties and debates, some of which are addressed below.

What do we know about growth factors in milk of treated animals?

The wholesomeness of milk is not affected by rbGH treatment. However, some subtle changes do take place in the treated animal. The growth hormone typically acts by triggering the cells to make other chemicals, called growth factors. These growth factors actually cause the increase in growth rate and milk production. Milk from rbGH-treated cattle has been found to have slightly higher levels of the naturally produced protein called insulin-dependent growth factor-1 (IGF-1). IGF-1 is a protein, and is digested into smaller pieces in the stomach.

Scientists at FDA have considered the evidence from studies of cancer risk in people who have naturally high body levels of IGF-1. Higher levels of IGF-1 in blood have been found in women with breast cancer compared to women without breast cancer in the Harvard-based Nurses' Health Study. Scientists are investigating if IGF-1 is just present at higher levels in breast cancer patients or if it has a role in increasing the risk for the disease. In laboratory studies, breast cancer cells growing on a plastic dish, grow at a faster rate when bathed in a solution containing IGF-1. However, IGF-1 also plays an important role in helping normal cells grow. Hence, from these few studies, we cannot conclude whether or not IGF-1 increases breast cancer risk.

FDA scientists have concluded that IGF-1 in milk is unlikely to present any human food safety concern for the following reasons: 1) IGF-1 levels in cow's milk from untreated animals vary in nature, depending on the number of calves and the lactation stage; 2) IGF-1 is also present in human breast milk, at levels higher than in hormone-treated cow's milk; 3) IGF-1 in milk is not expected to act as a growth factor in people who drink it because it gets digested in the stomach; 4) IGF-1 needs to be injected into the blood to have a growth-promoting effect; and 5) increased IGF-1 levels in food are not expected to result in higher blood levels of IGF-1 in humans who eat the food.

Concern about milk-related allergies

A detailed discussion of this topic is beyond the scope of this fact sheet. A brief outline of the issue is presented here, along with references for more information.

Digested or broken down fragments of proteins absorbed through the stomach can cause the immune system to produce antibodies, which sometimes can lead to milk-related allergies. There have been studies done to investigate whether the immune system can react to fragments of rbGH and IGF-1 absorbed through the stomach. Reviewers of these studies at Health Canada (the Canadian counterpart to FDA) expressed a concern that in one study, some of the laboratory rats that were fed high levels of rbGH for 90 days developed antibodies against it (http://www.hc-sc.gc.ca/english/archives/rbst). Scientists at FDA evaluated these studies in rats and concluded that only animals that were fed a very large amount of rbGH in food produced antibodies against it. Such large amounts of rbGH are not expected to occur in the milk that humans drink ("Report on the Food and Drug Administration's Review of the Safety of Bovine Somatotropin" available at: http://www.fda.gov/cvm; a copy of this report can be requested by calling: 310-574-1755).

Studies have also looked at whether IGF-1 fed to laboratory rats and digested in the stomach can affect the immune system. No immune effects were observed in these studies, but the animals were fed IGF-1 for only two weeks. No studies have been done on the effects of feeding rats or other experimental animals with IGF-1 over longer periods of time.

Are hormone-treated animals healthy?

There is a concern that because of increased milking, hormone-treated cows may become more prone to infection of the udders, called mastitis. This could lead to more antibiotics being used to treat the cows, in turn leading to more residues of antibiotics to remain in the milk. Frequent exposure to antibiotic residues through milk or dairy products is a health concern for people over the long term. In the normal body, there are bacteria that live in the gut and mouth and help in the digestion of food in the gut. These "friendly" bacteria do not normally cause disease since the immune system keeps them in check. However, if the immune system is weak, these "friendly" bacteria can invade tissues and cause infection. Bacteria in the normal body that come across small amounts of antibiotics frequently, can develop ways to survive the antibiotics and become "antibiotic resistant." In cases of infection and illness, it then

becomes more difficult to control such resistant bacteria with the available antibiotics.

Some increase in incidence of antibiotic residues was observed in cow's milk following the use of rbGH. At the same time as rbGH started being used, some of the major dairy states in US switched over to a new and improved method to test for antibiotic residues. It is difficult to determine whether the increase in incidence of antibiotic residues in milk was due to increased use, or better testing methods. New York State (NYS) was one of the states that had not changed its method to test for antibiotic residues in milk at that time. The incidence of antibiotic residues in milk from NYS was not found to be higher after the approval of rbGH use. This suggests that the increased incidence of antibiotic residues observed in some states may have been due to better testing methods rather than an increase in use of antibiotics for treatment of mastitis. An Expert Committee at FDA's Center for Veterinary Medicine has concluded that while rbGH use may cause a slight increase in mastitis, dairy management practices that are currently in use should prevent any increase in antibiotic residues in milk.

Are growth hormones used elsewhere in the world?

The debate on whether growth hormones should or should not be used for food production has become a very political issue. In 1989, the European Community (now European Union) issued a ban on all meat from animals treated with steroid growth hormones, which is still in effect. The use of steroid hormones for beef cattle is permitted in Canada.

Countries within the European Union do not allow the use of the protein hormone rbGH, for dairy cattle. In 1999, the Canadian government refused approval for the sale of rbGH for dairy cattle, based on concerns about the health effects including mastitis in treated animals.

Conclusions

Studies done so far do not provide evidence to state that hormone residues in meat or dairy products cause any human health effects. However, a conclusion on lack of human health effect can only be made after large-scale studies compare the health of people who eat meat or dairy products from hormone-treated animals, to people who eat a similar diet, but from untreated animals.

Where is more research needed?

Some of the consumer concerns in this fact sheet cannot be answered conclusively without further studies:

- Exposure to hormones in meat was suspected as the cause for early puberty in girls in Puerto Rico and Italy, but was never verified. To conclusively answer the question, large-scale epidemiological studies would be needed to compare the age of puberty in girls who eat meat from hormone-treated animals to those who eat meat from untreated animals. Such studies would need to make sure that other known influences that affect the age of puberty in girls are not playing a role.

- Short-term studies in laboratory rats have not indicated a concern about milk-related allergies or immune effects from exposure to rbGH or IGF-1 in milk or dairy products. However, short-term studies cannot be used to rule out all possibilities of any immune, or unexpected health effects after long-term exposure. Studies in laboratory animals on effects of life-long exposure to milk from rbGH-treated cows may help answer this question.

Some healthy diet tips that also help reduce exposure to hormones used in food production

While currently available evidence does not indicate a link between eating meat, milk or dairy products from hormone-treated animals and any health effects, adopting some known healthy diet habits (see below) can help reduce exposure to hormones used in meat, poultry and dairy production.

- Eat a varied diet, rich in fruits, grains and vegetables.
- Eat meats in moderation, well cooked, but not charred.
- Eat more lean muscle meat, less liver and fat.

Note: Other BCERF Fact Sheets discussthe research on the relationship between eating dairy products, meat, poultry and fish, and the risk of breast cancer: (See BCERF Fact Sheet # 33 *Dairy Foods and the Risk of Breast Cancer* and BCERF Fact Sheet #39 *Meat, Poultry and Fish and the Risk of Breast Cancer.*

An extensive bibliography on *Consumer Concerns About Hormones in Food* is available on the BCERF web site: http://www.cfe.cornell.edu/bcerf/

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